Medical Products Manufacturing, Inc.
1775 Gunnison
Delta, CO 81416

AUG 1 8 2006

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 ~~and 21 CFR 807.92~~.

The assigned 510(K) number is : K06 1560

Description:
The Sonomark® accessory to Diagnostic Ultrasound Transducers is a skin-marking attachment.

Substantial Equivalence:
Substantial equivalence has been demonstrated between the Sonomark® accessory, the AiM Accuracy in Marking® System (510(k) No.: K053463).

Intended Use:
This accessory device is intended to be used for skin marking when used with various diagnostic ultrasound transducers.

Manufacturer:	Medical Products Manufacturing, Inc. (MPM) and Innovative Manufacturing Company (IMC)
Address:	1775 Gunnison Delta, CO 81416
Corresponding Official:	Theron E. Johnson
Title:	President & CEO
Address:	11495 – 3800 Road Paonia, CO 81428
Telephone	970-527-7879
Initial Distributor:	Same as Manufacturer
Device Name:	Sonomark®
Common Name	Accessory to a Linear Diagnostic Ultrasound Transducer

K061560

Classification:	Regulatory Class: II, Review Category: Tier II Diagnostic Ultrasound Transducer FR Number: 892.1570 Product Code: 90-ITX
Establishment Registration No.:	To be obtained following 510(k) clearance
514 Performance Standard:	None
Special Controls:	None for accessory device
Prescription Status:	Accessory to Prescription Device
Manufacturing Location:	1775 Gunnison Delta, CO 81416
Sterilization Site:	Not applicable
Reason for Submission:	Notification of intent to market accessory device in US
Submission Track:	Not applicable for accessory device

Indications for Use

The Sonomark® accessory to linear diagnostic ultrasound transducers is indicated for diagnostic ultrasound procedures to mark anatomical features.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG 18 2006

Mr. Theron E. Johnson
CEO & President
Medical Products Manufacturing, Inc. and
Innovative Manufacturing Company
11495 – 3800 Road
PAONIA CO 81428

Re: K061560
Trade/Device Name: Sonomark®
Regulation Number: 21 CFR §892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Codes: ITX
Dated: May 24, 2006
Received: June 5, 2006

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061560

Device Name: Sonomark®

Indications For Use:

The Sonomark accessory to linear diagnostic ultrasound transducers is indicated for diagnostic ultrasound procedures to mark anatomical features.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lagerman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061560